PB87-180485

Creosote and Coal Tar (Non-Wood) Decision Document

(U.S.) Environmental Protection Agency
Washington, DC

2 Oct 85

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. Recipient's Accession No. PB87 180485/AS

4. Title and Subtitle

CREOSOTE AND COAL TAR (NON-WOOD): DECISION DOCUMENT

5. Report Date
OCTOBER 2, 1985

6.

7. Author(s)
EPA, OPP, REGISTRATION DIVISION

8. Performing Organization Rept. No.
540/09-87-130

9. Performing Organization Name and Address

ENVIRONMENTAL PROTECTION AGENCY
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WASHINGTON, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address

SAME AS #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This Position Document addresses the risks and benefits of pesticide products containing the subject active ingredient. The Agency has determined that the use of products containing the subject active ingredient may meet or exceed a risk criterion described in 40 CFR Part 154. Potential hazards will be examined further to determine the nature and extent of the risk, and considering the benefits of the subject active ingredient, whether such risks cause unreasonable adverse effects on the environment.

17. Document Analysis a. Descriptors

PESTICIDES, STANDARDS, REGULATIONS, MANUFACTURING, CHEMISTRY, TOXICOLOGY, RESIDUES, ECOLOGY, PATH OF POLLUTANTS

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement:	19. Security Class (This Report)	21. No. of Pages
PUBLICLY AVAILABLE	UNCLASSIFIED	50
	20. Security Class (This Page) UNCLASSIFIED	22. Price

PB87-180485

DECISION DOCUMENT: CREOSOTE AND COAL TAR FOR NONWOOD PRESERVATIVE USES

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
OCTOBER 2, 1985

REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL
INFORMATION SERVICE
SPRINGFIELD, VA 22161

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ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

[OPP-30000/28J]

INTENT TO CANCEL REGISTRATIONS OF PESTICIDE PRODUCTS CONTAINING CREOSOTE AND COAL TAR FOR NONWOOD PRESERVATIVE USES

AGENCY: Environmental Protection Agency.

ACTION: Notice of Intent to Cancel.

SUMMARY: On October 18, 1978, EPA initiated an administrative review process to consider whether the pesticide registrations for all registered uses of creosote, coal tar, and coal tar neutral oil (CTNO) should be cancelled or modified. EPA issued a Special Review Position Document 2/3 setting forth the Agency's preliminary determination regarding the risks and benefits associated with nonwood preservative uses of these pesticides for all registered uses which was published in the FEDERAL REGISTER of August 22, 1984 (49 FR 33328). This Notice announces the Agency's final decision to cancel registrations of all nonwood preservative uses of creosote and coal tar except for the use to control gypsy moth egg masses, and to defer the regulatory decision on the nonwood preservative uses of coal tar neutral oil (CTNO) until more data are obtained.

DATE: Requests for a hearing by a registrant, applicant, or other adversely affected person must be received by (insert date 30 days after date of publication in the FEDERAL REGISTER) or, for a registrant or applicant, within 30 days from

receipt by mail of this Notice, whichever date is later.

ADDRESS: Requests for a hearing must be submitted to:

Hearing Clerk (A-110),
Environmental Protection Agency,
401 M St., SW.,
Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: By mail:

Paul Parsons,
Registration Division (TS-767C),
Office of Pesticide Programs,
Environmental Protection Agency
401 M St., SW.,
Washington, D.C. 20460
Office Location and telephone number:
Rm. 711 Crystal Mall #2,
1921 Jefferson Davis Highway,
Arlington, VA 22202,
(703-557-1632).

SUPPLEMENTARY INFORMATION:

I. INTRODUCTION

The Environmental Protection Agency issued a notice of rebuttable presumption against registration (hereafter referred to as Special Review) for the uses of pesticide products containing creosote, coal tar, and coal tar neutral oil (CTNO), which was published in the FEDERAL REGISTER of October 18, 1978 (43 FR 48154).

Issuance of the Notice initiated the Agency's Special Review of the risks and benefits of these products. The Special Review was issued on the basis of oncogenicity and mutagenicity. The Special Review Position Document 1 (PD 1) issued with the notice of rebuttable presumption describes in detail the studies that formed the basis for the presumption. In January 1981 a Position Document 2/3 (PD 2/3) addressed the risks and benefits of the wood preservative uses of creosote, coal tar, and CTNO, the inorganic arsenicals, and pentachlorophenol.

A Position Document 4 (PD 4) was published in the FEDERAL REGISTER of July 13, 1984 (49 FR 28666) on the wood preservative uses of creosote, coal tar and CTNO, the inorganic arsenical compounds and pentachlorophenol. It set forth the Agency's final position on the regulation and use of these chemicals as wood preservatives. EPA announced in the FEDERAL REGISTER of August 22, 1984 (49 FR 33328) the availability of Position Document 2/3 (PD-2/3-nonwood) and the Agency's proposed decision to cancel registrations of all nonwood preservative uses of creosote, coal tar, and CTNO.

This Notice concludes the Special Review process and announces the Agency's final decision to cancel registrations of all nonwood preservative uses of creosote and coal tar, except for use to control gypsy moth egg masses, and to defer the regulatory decision on the nonwood preservative uses of CTNO until more data are obtained.

In summary, the Agency has determined that all the nonwood preservative uses of creosote and coal tar meet or exceed the risk criteria outlined in 40 CFR 162.11. The Agency has also analyzed the economic, social, and environmental benefits of these uses. In balancing risks and benefits, the Agency considered whether the risks of each use are outweighed by the benefits of the use, what risk reductions could be achieved, and how risk reduction measures would affect the benefits of the use. The Agency has determined that the risks of all but one of the nonwood preservative uses are greater than the social, economic, and environmental benefits of these uses. Accordingly, the Agency is denying applications and cancelling the registration of creosote and coal tar products for the following uses:

Herbicidal Use:	Nutgrass control in ornamental flowering plants and lawns
	Product storage yards
	Agricultural premises and highway rights-of-way
Fungicidal Use:	Rope and canvas
Disinfectant Uses:	Livestock premises
	Poultry premises
	Home and institutional uses
	Transportation vehicles
	Tree wound dressing
Insecticidal and Miticidal Uses:	Insect repellent
	Animal repellent
	Screwworm control
	Bird repellent
	Animal dip

The Agency is returning the registrations of creosote and coal tar products for control of gypsy moth egg masses to the normal registration process because: usage and exposure are low, there are no alternative control measures at this time, and there are potentially high benefits from this use. The Agency is requiring changes to the terms and conditions of registration of this use to further reduce applicator exposure and risk.

The Agency has also determined that a thorough review of available toxicological and chemistry data on CTNO shows that there is insufficient evidence at this time to conclude the Special Review on CTNO. The Agency is therefore deferring this decision until data are submitted to resolve the toxicological issues concerning CTNO. The Agency will require registrants of CTNO products to submit toxicology and other data on these products pursuant to FIFRA section 3(c)(2)(B). When the data are received and reviewed, the Agency will determine regulatory action.

This Notice is organized into six units. Unit I is this introduction. Unit II, entitled "Legal Background," provides a general discussion of the regulatory framework within which this action is taken. Unit III summarizes the risk and benefit determinations concerning the nonwood preservative uses of creosote, coal tar, and CTNO. Unit IV contains the comments of the Scientific Advisory Panel (SAP), the U.S. Department of Agriculture (USDA), registrants, and interested parties received in response to the Position Document 2/3 on the nonwood uses of creosote, coal tar, and CTNO, and the Agency's responses to

these comments. Unit V sets forth the regulatory actions required by this Notice. Unit VI, entitled "Procedural Matters," provides a brief discussion of the procedures which will be followed in implementing the regulatory actions which the Agency is announcing in this Notice.

II. LEGAL BACKGROUND

To obtain a registration for a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA"), an applicant for registration must show that the pesticide satisfies the statutory standard for registration. That standard requires, among other things, that the pesticide perform its intended function without causing "unreasonable adverse effects on the environment" (FIFRA section 3(c)(5)).

The term "unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide" (FIFRA section 2(bb)). This standard requires a finding that the benefits of each use of the pesticide exceed the risks of use, when the pesticide is used in accordance with commonly recognized practice and in compliance with the terms and conditions of registration.

The burden of proving that a pesticide satisfies the registration standard is on the proponents of registration and continues as long as the registration remains in effect. Under section 6 of FIFRA, the Administrator may cancel the registration whenever it is determined that the pesticide causes unreasonable adverse effects on the environment. The Agency created the

RPAR process, now known as the Special Review process, to facilitate the identification of pesticide uses which may not satisfy the statutory requirements for registration and to provide an informal procedure to gather and evaluate information about the risks and benefits of these uses.

A Special Review is commenced if a pesticide meets or exceeds risk criteria set out in the regulations at 40 CFR 162.11. The Agency announces that a Special Review is initiated by issuing a notice for publication in the FEDERAL REGISTER. Registrants and other interested persons are invited to review the data upon which the review is based and to submit data and information to rebut the presumption by showing that the Agency's initial determination of risk was in error, or by showing that use of the pesticide is not likely to result in any significant risk to humans or the environment. In addition to submitting evidence to rebut the risk presumption, commenters may submit evidence as to whether the economic, social and environmental benefits of the use of the pesticide outweigh the risks of use. Unless all presumptions of risk are rebutted, the Special Review is concluded by issuance of a Notice of Intent to Cancel.

In determining whether the use of a pesticide poses risks which are greater than the benefits, the Agency considers possible changes to the terms and conditions of registration which can reduce risks, and the impacts of such modifications on the benefits of use. If the Agency determines that such changes reduce risks to the level where the benefits outweigh the risks, it may require that such changes be made in the terms

and conditions of the registrations. Alternatively, the Agency may determine that no change in the terms and conditions of a registration will adequately assure that use of the pesticide will not pose any unreasonable adverse effects. If the Agency makes such a determination, it may seek cancellation, and, if necessary, suspension. In either case, the Agency may issue a Notice of Intent to Cancel the registrations. If the Notice requires changes in the terms and conditions of registration, cancellation may be avoided by making the specified corrections set forth in the Notice, if possible. Adversely affected persons may also request a hearing on the cancellation of a specified registration and use, and if they do so in a legally effective manner, that registration and use will be maintained pending a decision at the close of an administrative hearing.

III. SUMMARY OF RISK AND BENEFIT DETERMINATIONS

A. INTRODUCTION

The Agency has carefully considered the information and evaluated the data submitted regarding the risks and benefits of continued nonwood use of creosote and coal tar. Detailed discussions of these risks and benefits are presented in the PD 2/3 nonwood uses of creosote and coal tar and the PD-4 for the wood preservative uses. This unit sets forth the Agency's summary of the risk determinations for the nonwood preservative uses of creosote and coal tar.

B. RISK DETERMINATIONS

Creosote and coal tar and many of their component chemicals have been well characterized as carcinogens in laboratory animals

(PD-1, Coal tar, Creosote, and Coal Tar Neutral Oils; PD-2/3 Wood Preservatives). These studies, along with the several reports in the literature of skin cancer in people exposed to creosote and coal tars, suggest that these chemicals are human carcinogens.

Data on the mutagenic activity of creosote and coal tar and the data regarding the mutagenic activity of the individual compounds identified in creosote and coal tar suggest that creosote and coal tar are potentially mutagenic in intact mammals including humans. Although creosote and coal tar are judged as potential mammalian mutagens which may cause somatic mutations (somatic mutations may be involved in the etiology of cancer), the data concerning genetic risk with respect to germ cells are too limited for any conclusions at present.

No data have been provided during this Special Review that rebuts these conclusions concerning the oncogenicity and mutagenicity of creosote or coal tar. Applicators of products containing creosote and coal tar used for nonwood purposes are subject to both dermal and inhalation exposure during the application process. The Agency has therefore determined that the use of products containing creosote and coal tar for all nonwood purposes poses a risk of oncogenic and mutagenic effects to the applicators.

CTNO has not been specifically tested for oncogenicity or mutagenicity. The Agency concludes that it is inappropriate to extrapolate the risks of CTNO from data on creosote or coal tar. Nevertheless, the Agency remains concerned about the potential carcinogenicity and mutagenicity of CTNO, considering

its derivation from or similarity to materials known to be carcinogenic and mutagenic, (i.e. coal tar and creosote). This issue is discussed further in Unit IV.A.2.

C. BENEFIT DETERMINATIONS

The risks of all nonwood preservative uses of creosote and coal tar are of sufficient magnitude to require the Agency to determine whether these uses offer offsetting social, economic, or environmental benefits.

The nonwood uses of creosote and coal tar fall into four categories: herbicidal uses, fungicidal use, insecticidal uses, and disinfectant uses. Creosote and coal tar are ingredients in products registered as a foliar spray to control weeds and grass. As a fungicide, creosote and coal tar are registered for use on rope and canvas products. As a disinfectant, creosote and coal tar are used to control fungi and bacteria in poultry and livestock areas, and on tree wound dressings. Their insecticidal uses include the treatment of gypsy moth egg larvae, and use as a repellent. These nonwood preservative uses of creosote and coal tar represent approximately two percent of the total amount of creosote and coal tar produced. Except for the gypsy moth egg mass use, there are efficacious, economically competitive alternative products for all uses. Moreover, as discussed below, the Agency believes that there are few or no products actually being sold for the non-wood registered uses. Thus, cancellation of these registrations would have no adverse economic or social impact.

The projected impacts of the cancellation of these registrations are discussed at length on pp.III-1-13 of the PD 2/3 (nonwood).

A brief summary of the projected economic impact for each use is provided below.

1. Herbicidal uses.- a. Ornamental plants and lawns. Creosote is currently registered as a herbicide for use on ornamental flowering plants and lawns to control nutgrass. However, the Agency is unaware of any current use of creosote for this purpose. Because there are registered, efficacious, and economically competitive alternative products, cancellation of this use is expected to have no economic impact.

b. Product storage yards. Creosote and coal tar have limited use to control weeds and grass on product storage yards. There are efficacious and economically competitive alternative products available and cancellation of this use is expected to have no economic impact.

c. Agricultural premises and highway rights-of-way. Creosote is registered for use on agricultural premises and along highway rights-of-way for general weed control. The Agency has no information on the extent of current use. Because of the number of efficacious, economically competitive alternative products available, the Agency concludes that there will be no economic impact from cancellation of this use.

2. Fungicidal (rope and canvas). Creosote is registered for use as a fungicide on rope and canvas. However, the

Agency believes that cancellation of this use would have no economic impact because there are efficacious, economically competitive alternatives available.

3. Disinfectant uses-- a. Livestock premises. Creosote and coal tar are used as livestock disinfectants. However, since efficacious, economically competitive alternatives are available, cancellation of this use would not have a significant economic impact.

b. Home and institutional use. Although several products are registered for home and institutional uses, actual use for these purposes is unlikely because the products have a strong unpleasant odor. Since efficacious, economically competitive alternatives are available, cancellation of this use would not have a significant economic impact.

c. Transportation vehicles. Although products are registered for use as disinfectants in transportation vehicles, the Agency knows of no actual use for these purposes.

d. Tree wound dressings. Although creosote is registered for use as a tree wound dressing, the Agency has no evidence of current use. Cancellation of this use would therefore not be expected to have a significant economic impact.

4. Use as larvicide, insecticide, and repellent--

a. Insect repellent. Coal tar is currently registered for use as an insect repellent. However, there is no evidence that such products are currently being marketed and so cancellation

would not have a significant economic impact. There are efficacious, economically competitive, alternative products registered for this use.

b. Animal repellent. Creosote products are registered as animal repellents but the Agency has not been able to obtain information on the extent of use. The Agency believes that creosote products are in current use to prevent cribbing by horses on wooden structures. There are efficacious, economically competitive alternative control measures for this use and cancellation would not have a significant economic impact.

c. Screwworm control. One product is registered for screwworm control, but actual use of the product cannot be confirmed. Cancellation of this use is therefore not expected to have a significant economic impact.

d. Insect control. Coal tar products are registered to control maggots and flies. However, efficacious and economically competitive alternatives are available. Therefore, the cancellation of this use would not have a significant impact.

e. Animal dip. Coal tar distillates have been used for more than a century to control parasites on animals. However, there are numerous registered alternative products. Therefore, the cancellation of this use would not have a significant impact.

f. Bird repellent. Coal tar products are used to treat seed to prevent birds from eating it. Efficacious, economically competitive chemical and non-chemical alternatives are available,

and therefore, the cancellation of this use would not have a significant impact.

g. Gypsy moth control. Creosote products are used by the USDA Plant Protection and Quarantine Program to destroy the egg masses of the gypsy moth. Gypsy moth larvae have damaged extensive acreages of forest in the northeastern United States. This pest has been expanding its range along a wide front to the south and west. One method of reducing its spread is to inspect outdoor products in transit for the presence of gypsy moth egg masses, and to destroy any egg masses that are found. This practice reduces the accidental introduction of this pest into non-infested areas. There are no currently registered alternative products with ovicidal activity for this use and cancellation could result in a significant economic impact.

IV. COMMENTS OF REGISTRANTS AND OTHER INTERESTED PARTIES, THE U.S. DEPARTMENT OF AGRICULTURE AND THE SCIENCE ADVISORY PANEL; AGENCY RESPONSES TO COMMENTS

A. COMMENTS OF REGISTRANTS AND OTHER INTERESTED PARTIES

1. General. The Agency received comments on the Position Document 2/3 from several registrants and users and from the Creosote Council of the American Wood Preservers Institute. All comments were considered in the preparation of this document. These comments fall into six general categories: the chemical identity of coal tar neutral oil; the adequacy of the Agency's toxicology assessment; the adequacy of the Agency's exposure assessment; the Agency's consideration of measures to reduce exposure to creosote, coal tar, and CTNO; the adequacy of the Agency's oncogenic and mutagenic risk

assessments; and, the adequacy of the Agency's benefit assessment. The following unit will discuss the comments in each of these categories, and present the Agency's responses to the comments.

2. The chemical identity of coal tar neutral oil (CTNO)--

a. Comment. In brief, the Creosote Council commented (pp. 2-15) that the CTNO tested in the toxicology studies the Agency used as the basis of the rebuttable presumption against CTNO is not the same substance used in currently registered pesticides. In addition, the Creosote Council stated that CTNO is not chemically similar to creosote or coal tar, and therefore, toxicological data concerning creosote or coal tar do not apply to CTNO. The Creosote Council provided some simplified information on the derivation of CTNO from coal tar, and on the chemical composition of CTNO. The information provided by the Creosote Council accounts for only 60 percent to 65 percent of the constituents of CTNO.

b. Agency response. Based on the information provided by the Creosote Council, the Agency now believes that the CTNO used in these early studies does not have the same composition as the CTNO used in currently registered products.

In the PD 2/3 (nonwood), the Agency summarized the evidence for the oncogenicity of CTNO:

> As with creosote and coal tar, dermal application of coal tar neutral oil has been shown to produce skin tumors in mice (Horton, 1961). Berenblum and Schoenthal

> (1947) found that several chromatographic fractions of coal tar neutral oil produced skin tumors when dermally applied to mice. Cabot et al. (1940) found that mixtures of coal tar neutral oil with benzo(a)pyrene produced fewer tumors than benzo(a)pyrene alone, but suggested that this inhibiting effect was due to skin damage. (p.II-13)

The early, poorly characterized material was apparently coal tar with the acids and bases removed. The CTNO currently marketed is a fraction or mixture of fractions of coal tar with a specific boiling range or ranges, from which the tar acids are removed and from which the tar bases may or may not be removed. This CTNO has not been tested for oncogenic or mutagenic potential. Furthermore, the Agency agrees that CTNO has not been chemically characterized sufficiently to make toxicological comparisons between CTNO and creosote or coal tar.

However, the Agency remains concerned about the possible oncogenicity and mutagenicity of CTNO, particularly in light of the unknown composition of 35 percent to 40 percent of CTNO and its derivation from or similarity to materials known to be carcinogenic and mutagenic, i.e. coal tar and creosote. Therefore, the Agency is deferring a regulatory decision on CTNO at this time. Additionally, toxicological and other data will be required under FIFRA section 3(c)(2)(B). The

Agency has issued a Data Call-In Notice (May, 1985) requiring registrants to submit product chemistry data on creosote, coal tar, and CTNO.

Because the regulatory decision on CTNO products is being deferred, rebuttal comments received pertaining to CTNO will not be addressed in this document. The Agency will consider these comments in the review of CTNO.

3. The adequacy of the Agency's toxicology assessment--

a. Comment. The Creosote Council commented (p. 17) that the toxicology assessment for the nonwood preservative uses of creosote and coal tar is similar to the toxicology assessment for the wood uses of creosote and coal tar. The Council stated that, therefore, since the toxicology assessment for the wood uses of creosote and coal tar has been rebutted, then the toxicology assessment for the nonwood preservative uses of creosote and coal tar is also rebutted.

b. Agency response. The Agency agrees that the toxicology assessment of the wood and the nonwood use of creosote are similar. These assessments are presented in the PD 2/3 (wood preservative) and PD 2/3 (nonwood). The Agency used the same data base for wood and nonwood uses of creosote and coal tar for hazard assessment because the creosote and coal tar used for both categories of use are virtually identical. However, the Agency does not agree that the toxicology assessment for the wood preservative uses of creosote and coal tar has been rebutted. As noted in the PD-4 for the wood preservative uses of creosote and coal tar:

> No new information was received by the Agency which changed the Agency's position regarding the rebuttable presumptions for creosote. As summarized in the PD 2/3 (pp. 36-46 and p. 85), creosote and many of its component chemicals have been shown to cause cancer in laboratory animals; there have also been many case reports linking human cancer to exposure to creosote.

The Agency has received no new information since the issuance of the wood preservative PD-4 or the issuance of the nonwood preservative PD 2/3 which alters the Agency's position on the oncogenic or mutagenic potential of creosote and coal tar. Therefore, the toxicology assessment of the nonwood preservative uses of creosote and coal tar has not been rebutted.

4. The adequacy of the Agency's exposure assessment --

a. Comment. The Creosote Council commented (pp. 20-21) that the Agency's exposure assessment is qualitative, not quantitative. The Creosote Council also commented (pp. 20-21) that the Agency's exposure assessment omitted estimates of the amount of creosote exposure from various pathways.

b. Agency response. The Agency agrees that its exposure assessment was qualitative and not quantitative. Because of the unique nature of creosote and coal tar, it was not possible

to provide a quantitative exposure assessment nor to estimate creosote exposure by different pathways. Creosote and coal tar are heterogeneous mixtures of a multitude of organic components, which vary not only when the creosote and coal tar are prepared from different sources, but also within batches from the same source. This heterogeneity poses extremely difficult problems in chemical and risk analysis and exposure sampling; these problems preclude a quantitative exposure assessment at this time. No information was provided which would make possible a qualitative exposure assessment, taking into account different exposure pathways.

c. Comment. The Creosote Council commented (p. 22) that the Agency's qualitative exposure assessment assumes complete human uptake of creosote.

d. Agency response. The Agency disagrees with this interpretation of its exposure assessment. At no point in the exposure assessment is complete human uptake of creosote or coal tar stated as an assumption. The Agency assumed that there is some uptake, since as discussed in the PD 2/3 (non-wood) (pp.II-18-19), human and animal exposure studies clearly show exposure to creosote and coal tar leads to adverse effects.

e. Comment. The Creosote Council commented (pp. 20;22-23) that the Agency has not justified its exposure assumptions, basing them instead on product labeling.

f. Agency response. The Agency has stated that the exposure assumptions are based on label directions of creosote and coal tar products because this was the only available information. It is reasonable to use this information because labeling directions indicate application rates and methods, concentrations of pesticide, and other information used in preparing exposure assessments. No further information has been provided to refine or change these assumptions.

g. Comment. The Creosote Council commented (pp. 22-23) that the Agency has not defined the qualitative terms used in the exposure assessment to classify exposure.

h. Agency response. The Agency used the words high, medium, and low to classify exposure potential in the PD 2/3 (nonwood). These words represented the Agency's best description for estimating exposure at that time. As explained in Agency response 4.b. above, the heterogeneity of creosote and coal tar precludes a quantitative description at this time. These terms are based on the Agency's consideration of exposure factors that include: frequency of use by the applicator, protective clothing likely to be used or required by label directions, concentration of the product used, and application method. While these words do not convey a quantitative estimate, they do attempt to indicate the Agency's estimate of exposure levels. No information has been provided to allow more precise classification.

i. Comment. The Creosote Council commented (pp. 18-20) that the Agency's exposure assessment does not follow the proposed guidelines for exposure assessment (49 FR 46304).

j. Agency response. The Agency believes the Creosote Council has misinterpreted the proposed exposure quidelines. The proposed guidelines are a suggested format for assessing exposure. They are not specific nor do they represent specific methodologies. Quantitative exposure estimates are not required in the guidelines. Absence of quantitative data does not preclude a qualitative assessment based on the available information.

5. The Agency's consideration of measures to reduce exposure to creosote and coal tar--a. Comment. The Creosote Council commented (pp. 25-27) that the Agency did not adequately consider regulatory measures to reduce exposure to creosote and coal tar.

b. Agency response. The Agency considered regulatory measures to reduce exposure to creosote and coal tar, as discussed on pp. IV-2-9 in the PD 2/3 (nonwood). These measures included use of impermeable gloves, use of respirators and coveralls, disposal of protective gloves, use of respirators and coveralls, disposal of protective clothing, and other measures. The Agency believes that the risks of the nonwood preservative uses of creosote and coal tar could be reduced by use of protective clothing and other measures. However, the benefits of these uses are very small; for some uses it cannot be determined if there is any usage. In light of the

small benefits and the availability of adequate alternative pesticides, the Agency has determined that even if measures were taken to reduce exposure to creosote and coal tar, the remaining risks of these uses outweigh the benefits.

6. The adequacy of the Agency's oncogenic and mutagenic risk assessment-- a. Comment. The Creosote Council commented (p. 28) that the Agency did not present quantitative data on dose response for the oncogenic risks of creosote and coal tar.

b. Agency response. As stated in PD 2/3 (nonwood), creosote and coal tar and many of their component chemicals are well characterized as carcinogens (p. II-54). Also, there is strong evidence from individual case studies that creosote and coal tar are potential human carcinogens. However, because of the variable composition of creosote and coal tar, the data are not appropriate quantitative risk estimates.

As set forth in PD 2/3 (nonwood), creosote and coal tar are complex blends of hundreds of constituents, including carcinogens, promoters, initiators and inhibitors. Because of the complexity of creosote and coal tar and the variable nature of the commercial materials, the quantitative estimation of risk will require special inhalation and dermal studies in laboratory animals. These studies will need to employ special sampling techniques to assure that test materials are truly representative of the chemicals to which people are actually exposed from the use of creosote and coal tar. However, it is clear from the large

number of laboratory studies on creosote and coal tar and their individual components that these materials are carcinogenic. In addition, exposure to applicators, based on consideration of use patterns is sufficient to cause the Agency to have significant concern about the continued nonwood preservative use of creosote and coal tar.

c. Comment. The Cresote Council commented (pp. 28-29) that the Agency did not present quantitative data on the mutagenic risk of creosote and coal tar. The Creosote Council further commented that the mutagenic risk assessment therefore does not meet the minimum standards of the proposed mutagenicity guidelines.

d. Agency response. The Agency agrees that it did not present quantitative data on the mutagenic risk of creosote and coal tar. However, it should be stressed that the available data on the mutagenicity of creosote and coal tar were appropriate only for hazard identification, not for a quantitative assessment, as stated on pp. II-53 of PD 2/3 (nonwood). The Agency views mutagenicity assessment as a multi-step process of which the first step is a hazard identification or a qualitative evaluation of data to determine the likely potential of an agent or a chemical to be mutagenic to humans. Available data indicate that creosote and coal tar are mutagenic in some microbial tests.

Furthermore, the Creosote Council has possibly misinterpreted the Agency's proposed guidelines, which state that "...often, no further data will be available [other than that for hazard identification] and judgments will need to be based on mainly qualitative criteria."

e. Comment. The Creosote Council commented (p. 29) that the proposed mutagenicity risk guidelines (49 FR 46315) emphasize that experimental animal data are not directly relevant to human experience because "...the experimental data on induced mutation frequency are usually obtained at exposure levels much higher than those that will be experienced by human beings." Accordingly, they state that the risk guidelines specify that it is necessary to extrapolate the induced mutation or carcinogenic frequency downward to approximate human dose-response. Thus, the Creosote Council believes the Agency has exaggerated the human dose-responses by not performing such a downward extrapolation.

f. Agency response. The mutagenicity guidelines do not state that "experimental animal data are not directly relevant to human experience...." The Creosote Council has possibly misinterpreted the guidelines. The guidelines state that, in extrapolating from animal data to human exposure situations, high-dose to low-dose extrapolation may be required. The Agency agrees that the downward extrapolation may well be required in quantitative assessments. However, this rebuttal comment does not apply to the mutagenicity assessment on creosote and coal tar, since only a qualitative assessment was conducted.

g. Comment. The Creosote Council commented (p. 30) that in evaluating mutagenic activity, the proposed mutagenicity risk guidelines state that "... greater weight will be attributed to tests conducted in germ cells than in somatic cells."

e. Comment. The Creosote Council commented (p. 29) that the proposed mutagenicity risk guidelines (49 FR 46315) emphasize that experimental animal data are not directly relevant to human experience because "...the experimental data on induced mutation frequency are usually obtained at exposure levels much higher than those that will be experienced by human beings." Accordingly, they state that the risk guidelines specify that it is necessary to extrapolate the induced mutation or carcinogenic frequency downward to approximate human dose-response. Thus, the Creosote Council believes the Agency has exaggerated the human dose-responses by not performing such a downward extrapolation.

f. Agency response. The mutagenicity guidelines do not state that "experimental animal data are not directly relevant to human experience...." The Creosote Council has possibly misinterpreted the guidelines. The guidelines state that, in extrapolating from animal data to human exposure situations, high-dose to low-dose extrapolation may be required. The Agency agrees that the downward extrapolation may well be required in quantitative assessments. However, this rebuttal comment does not apply to the mutagenicity assessment on creosote and coal tar, since only a qualitative assessment was conducted.

g. Comment. The Creosote Council commented (p. 30) that in evaluating mutagenic activity, the proposed mutagenicity risk guidelines state that "... greater weight will be attributed to tests conducted in germ cells than in somatic cells."

They further claimed that in PD 2/3 (nonwood) the Agency acknowledged that its information regarding germ cells is so limited that it cannot make any conclusions regarding mutagenicity and that its somatic mutation information is equivocal.

h. Agency response. The Agency agrees that greater weight will be attributed to tests conducted in germ cells and also to studies conducted in mammalian cells. However, this statement should not be misinterpreted to mean that studies in somatic cells should be disregarded. Creosote was tested in mammalian cells in culture and showed positive results. The gene mutation data on mammalian cells in vitro and in bacteria are not equivocal but strongly suggest that creosote and coal tar are mutagenic in mammalian cells.

7. The adequacy of the Agency's benefits assessment--

a. General. Since the regulatory decision on CTNO is being deferred, several of the nonwood preservative uses for which only CTNO is used are not under consideration in this document. These uses are:

Disinfectant uses:

Seed potato storage premises and equipment

Use as larvicide, insecticide, repellent:

Mosquito larvicide

Comments concerning these uses will not be addressed in this document. Uses for which creosote, coal tar, and CTNO are all registered will be discussed but these discussions apply only to the use of creosote and coal tar, not CTNO.

The Creosote Council commented on four issues concerning the Agency's benefit assessment of the nonwood uses of creosote and coal tar. These issues will be discussed and responded to individually. No comments supporting cancellation of the nonwood preservative uses of creosote and coal tar were received.

b. Comment. The Creosote Council commented (p. 32) that the Agency has not weighed the loss of the benefits resulting from the cancellation of the nonwood uses of creosote and coal tar against the risks of these uses.

c. Agency response. The Agency disagrees with this comment. The Agency has weighed the risks and benefits of the nonwood preservative uses of creosote and coal tar and has determined that the risks outweigh the benefits of these uses. These determinations are discussed on pp. V-1 through V-12 of the PD 2/3 (nonwood). No new information has been submitted, neither concerning risks nor benefits, that would cause the Agency to change these determinations.

d. Comment. The Creosote Council commented (p. 32) that the Agency has not considered the small producers who would be put out of business if the nonwood uses of creosote and coal tar were cancelled.

e. Agency response. The Agency assumes that the Creosote Council is referring to small pesticide producers, since no evidence has been submitted to show that small agricultural producers would be significantly affected by these cancellations. As stated in the Health Risk and Economic Impact Assessment

of Suspected Carcinogens: Interim Procedures and Guidelines published in the FEDERAL REGISTER of May 25, 1978 (41 FR 21402).

> The principal concern in the economic analysis will be the assessment of economic impacts on pesticide users and on the consumers of the products of the users. The impacts on pesticide manufacturers are not germane to this type of regulatory decision, in which the risk of the use of a pesticide is compared to the benefit of those uses.

Therefore, in accordance with the Agency's interim guidelines, the Agency did not consider the economic impact of the proposed cancellation on small pesticide producers.

f. Comment. The Creosote Council commented (pp. 32-33) that the Agency ignored the benefits information contained in joint USDA/EPA/State Biologic and Economic Assessment. The Creosote Council further commented that, according to the Assessment report, "...for at least five uses (disinfectant in animal quarters; control of drain flies; control of equine cribbing; bird repellent; and control of gypsy moth egg masses), there are no pesticidal alternatives, or only alternatives that are less effective or pose greater environmental risks."

g. Agency response. The Agency based much of its benefits analysis for the nonwood preservative uses of creosote and coal tar on the USDA/EPA/State Assessment; the Agency's conclusions in the PD 2/3 (nonwood) were largely in agreement

with the Joint Assessment. Regarding the uses the Creosote Council believes that the Joint Assessment identifies as having no alternatives, or less efficacious or riskier alternatives, the Joint Assessment states:

> The uses described above are minor compared with the major uses as a wood preservative. Among these minor uses, however, there are only five that are significant. They are as follows: Control of drain flies; and gypsy moth control; (these two have no registered alternatives), horse cribbing; disinfectant in animal quarters; and as a bird repellent. (These latter three have strong user support, although there are effective registered alternative pesticides for control).

Of these five uses, horse cribbing (i.e. animal repellent), animal quarter disinfectant, and bird repellent, are clearly identified in the Joint Assessment as having effective registered alternatives. One product is currently registered for drain fly control. The active ingredient in this product that actually controls against drain flies has been determined to be orthodichlorobenzene, and not creosote or coal tar. Furthermore, the registrants of this product

have amended this registration such that it no longer contains creosote or coal tar. The gypsy moth egg mass use is discussed in the following Unit IV.A.7.h.

h. Comment. Concerning the use of creosote and CTNO to control gypsy moth egg masses, the Creosote Council commented (p.36) that the Agency, citing USDA use of these products, ...states that the use of these products is environmentally sound because these two products prevent the future use of large amounts of pesticide to control the problem."

i. Agency response. The Agency believes that the Creosote Council has misunderstood the Agency's position. The PD 2/3 (nonwood) does not state that the use of creosote or CTNO to control gypsy moth egg masses is environmentally sound. Rather, the PD 2/3 (nonwood) states (p. II-13) that the USDA believes that this use is essential. The Agency did not agree, and noted that the USDA was researching alternative control methods. The Agency has received further information from USDA (see Section C, Comment 1 below) on this use since the issuance of the PD 2/3 (nonwood) and has reconsidered its position as discussed in Unit IV.B.

B. COMMENTS OF THE U.S. DEPARTMENT OF AGRICULTURE

The United States Department of Agriculture also responded to the PD 2/3 on the nonwood uses of creosote. The Agency carefully considered the USDA comments in the development of the final regulatory position. Specific issues that the USDA raises are numbered in brackets (e.g. [1]) and answered in the following section. The USDA's comments in their entirety were:

Mr. Steven Schatzow, Director
Office of Pesticide Programs
U. S. Environmental Protection Agency
Washington, D.C. 20460

Dear Mr. Schatzow:

This is in response to your letter of August 17 forwarding Position Document 2/3 on the non-wood preservative uses of coal tar, creosote and coal tar neutral oils.

[1.] As discussed verbally with Registration Division personnel the Department does not have any serious objection to the cancellation of most uses of these chemicals with one notable exception. The use of creosote is necessary for control of gypsy moth egg masses. Creosote is the only acceptable pesticide presently registered for this use. We have been actively involved in evaluating alternatives for this use and have been unable to find any material which provides sufficient efficacy for regulatory use and, until such time as acceptable alternative registered materials become available, the use of creosote should be maintained.

[2.] It is our opinion that the economic

analysis contained in the PD 2/3 is inadequate. It consists either of conclusory statements, with no supporting references, or of statements that no data are available. The benefits analysis does say that it is based on the assessment team report, but there is no indication in the text to support this claim. The economic analysis contains no numbers -- it does however acknowledge that a complete cost benefit analysis based on current usage data must be done before a final regulatory decision can be issued.

[3.] Similarly, while the agency does a credible job summarizing mutagenic and carcinogenic potential of the subject chemicals, without some type of quantitative evaluation of exposure and the resultant risk, the decisionmaker does not know if the risks of using creosote or coal tar for the proposed cancelled uses are any more or less than the risk to homeowners who clean their own chimneys or eat charcoal-broiled steaks. Many of the mutagenic or carcinogenic chemicals in creosote and coal tar are ubiquitous

in our environment. Consequently, some measure of incremental risk is necessary, even if crude because of uncertainties in cancer potency of creosote or coal tar mixtures.

We have a number of other minor comments on the document. At page III-13, for example, it states that "USDA recommends... Normally the USDA does not make "recommendations" therefore we would appreciate receiving a citation for this statement. We feel that the remainder of our comments would not be particularly useful until the agency corrects the major deficiencies.

Sincerely,

CHARLES L. SMITH
Coordinator, Pesticides &
Pesticide Assessment

C. AGENCY RESPONSE TO COMMENTS OF THE U.S. DEPARTMENT OF AGRICULTURE

Comment [1] -- Proposed cancellation. The Department of Agriculture does not object to proposed cancellation of most uses of creosote, coal tar, and CTNO with the exception of the use to control gypsy moth egg masses. USDA notes that creosote and CTNO are the only acceptable registered pesticides

for this use. In a later communication from Mr. Smith dated March 11, 1985, USDA informed the Agency that:

> The USDA's Animal and Plant Health Inspection Service requires treatment of certain household articles found infested with gypsy moth eggs pursuant to 7 CFR 301.45. These regulations were published in the Federal Register, on April 11, 1984 (40 FR 19951). Paragraph 301.45-12(a)(1)(2) of 7 CFR provides that outdoor articles may move in interstate commerce following certification by a qualified inspector. The inspector must certify that the outdoor household articles have been inspected and are free of any life stage of gypsy moth; or that the household article has been treated to destroy and life stages of gypsy moth in accordance with procedures prescribed in Section III.C.5 of the Appendix to the above regulation. The Appendix permits treatments with creosote, Spray-N-Kill, and Ficam A, as ovicides. All three of these were placed in our regulations because they were registered by EPA for that use. Spray-N-Kill contains acephate and Ficam A contains bendiocarb, neither of which provides ovocidal control.

> Experience indicates, and it is the opinion of our experts that only the creosote is effective for this use. Applications of creosote used under this regulation have been very limited. Less than 2 gallons of material have been used each year....

The Agency has reconsidered its proposed cancellation of this use, and will not cancel this use at this time, because: usage and exposure are low, there are no alternative control measures providing the needed ovicidal control at this time, there are potentially high benefits from this use.

Comment [2] -- Inadequacy of economic analysis. The Department of Agriculture stated that the economic analysis in PD-2/3 (nonwood) was inadequate and had no supporting references.

The economic analysis in the PD-2/3 was based on the USDA Assessment Team Report as well as reports prepared by the Mitre Corporation (EPA 1981) creosote, coal tar, and CTNO. There is a brief discussion in the text of the PD 2/3 (nonwood) (p. III-1) indicating that the benefit analysis was taken from these reports.

Also, USDA comments that a statement in the PD 2/3 (nonwood) "... acknowledges that a complete cost benefit analysis based on current usage data must be done before a final regulatory decision can be issued." This statement was made only with respect to the use of CTNO as a disinfectant in seed potato storage premises and equipment (p. III-4) and was put into the PD 2/3 (non-wood) document because available efficacy and benefits data did not indicate conclusively if this use is critical.

Comment [3] -- Inadequacy of risk analysis. USDA also commented that the risk analysis did not contain quantified risk estimates and, therefore, an incremental risk assessment was not done. As noted in the response to similar registrant comments, a quantitative risk assessment has not been done for any of the regulatory decisions on creosote, coal tar, and CTNO because of the chemical heterogeneity of these chemicals and because of the paucity of exposure data. No data were provided to refine these estimates.

D. COMMENTS OF THE SCIENTIFIC ADVISORY PANEL

The Scientific Advisory Panel held an open meeting on July 9, 1985, to review the Preliminary Notice of Determination concluding the Special Review for the nonwood use of creosote, coal tar, and coal tar neutral oil. At this meeting, the SAP heard a presentation by the Agency, the registrants, and other interested members of the public. The comments of the SAP are published in full below:

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA) SCIENTIFIC ADVISORY PANEL

Review of the Proposed Decision Options Being Considered to Conclude the Special Review of the Non-wood Uses of Creosote, Coal Tar, and Coal Tar Neutral Oil

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The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of the

proposed decision options being considered by the Agency to conclude the Special Review of the Non-wood Uses of Creosote, Coal Tar, and Coal Tar Neutral Oil. The review was conducted in an open meeting held in Alexandria, Virginia, on July 9, 1985. All Panel members were present for the review.

Public notice of the meeting was published in the FEDERAL REGISTER on Friday, June 21, 1985.

Oral and written statements were received from Koppers and from the Creosote Council of the American Wood Preservers Institute (AWPI).

In consideration of all matters brought out during the meeting and careful review of the materials presented by the Agency, by the AWPI, and by Koppers, the Panel unanimously submits the following report:

REPORT OF SAP RECOMMENDATION

The Scientific Advisory Panel (SAP) has reviewed the creosote, coal tar and coal tar neutral oil Position Document 2/3 prepared by EPA, as well as other materials, and responds as follows to the issue on coal tar neutral oil (CTNO).

Issue:

Although Coal Tar Neutral Oil (CTNO) is not well characterized, EPA believes the risks posed by CTNO are similar to those posed by coal tar and creosote. Do the members of the SAP agree and do they have any information that the risks posed by CTNO would differ from those posed by coal tar and creosote?

Response:

The Panel does not believe that the risks posed by CTNO are necessarily similar to those posed by coal tar and creosote. There are simply no data available on which the Panel can base an informed judgment.

The Panel believes that EPA should set forth clearly to the industry the toxicology and other data requirements which must be met for CTNO.

FOR THE CHAIRMAN:

Certified as an accurate report of Findings:

Philip H. Gray, Jr.

Executive Secretary

FIFRA Scientific Advisory Panel

Dated: July 29, 1985

E. AGENCY RESPONSE TO COMMENTS OF THE SCIENCE ADVISORY PANEL

The Agency agrees with the Science Advisory Panel, and will require registrants to submit toxicology and other data on CTNO.

V. INITIATION OF REGULATORY ACTIONS

1. Registered pesticide products. Based upon the assessment summarized in Unit IV, and discussed in detail in Position Documents 1 and 2/3, the Agency determines that all of the present nonwood preservative uses of creosote and coal tar (except the use to control gypsy moth egg masses) pose risks greater than the social, economic and environmental benefits of those uses. The Agency has determined that no modifications to the terms and conditions of registration for the nonwood preservative products will bring these products into compliance with the statutory standard for registration.

Therefore, the Agency is cancelling the registration of each of the following federally registered pesticide products for nonwood preservative uses containing the active ingredient creosote and coal tar whether registered under FIFRA sec. 3 or sec. 24(c):

Herbicidal Uses: Nutgrass control in ornamental flowering plants and lawns.

Product storage yards and lawns.

Agricultural premises and highway rights-of-way.

Fungicidal Uses: Rope and canvas.

Disinfectant Uses: Livestock premises.

Poultry premises.

Home and institutional uses.

Transportation vehicles.

Tree wound dressings.

Insecticidal Uses:

Animal repellent.

Screwworm control.

Animal dip.

Bird repellent.

Insect repellent.

The Agency has decided to continue the registrations of creosote and coal tar products registered to control gypsy moth egg masses since the benefits outweigh the risks of this use. The Agency has determined that change to the terms and conditions of registration of these products will further reduce the risks of this use.

In order to avoid cancellation, registrants of creosote or coal tar products for the gypsy moth egg mass use must file an amended application to modify the terms and conditions of registration to include certain information of their product labels.

The amended application must be filed within 30 days after publication of this Notice or within 30 days of receipt of this Notice, whichever occurs later.

The labels must be amended for the gypsy moth egg mass use of creosote and coal tar to include the following information:

Applicators must wear gloves impervious to the creosote or coal tar formulations (e.g., polyvinyl acetate (PVA), polyvinyl chloride (PVC), or neoprene) in all situations where dermal contact is expected.

Work clothing must be changed when it shows signs of contamination. Launder work clothing separately from other household laundry. Dispose of worn-out work clothing and or boots in any general landfill, in the trash, or in any other manner approved for pesticide disposal.

Avoid inhaling vapors.

Applicators must not eat, drink, or use tobacco products during those parts of the application process that may expose them to the creosote or coal tar treatment formulation. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.

Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use

according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

In addition, the Agency has determined that the product chemistry and toxicological data on coal tar neutral oil are insufficient at this time to allow a credible weighing of the risks and benefits of the uses of coal tar neutral oil. Nevertheless, the Agency remains concerned about the potential carcinogenic and mutagenic risks of CTNO. Therefore, the Agency has decided to defer the regulatory decision on CTNO. In the near future the Agency will issue a Data Call-In-Notice under section 3(c)(2)(B) of FIFRA requiring registrants to submit data to resolve the toxicological and other concerns about CTNO.

The Data Call-In Notice will require submission of the following studies to resolve the concerns of this Special Review regarding CTNO:

Mutagenicity :

Salmonella microsome plate incorporation test.

Mammalian gene mutation test in vitro.

Sister chromatid exchange in mammalian cells in vitro.

Carcinogenicity: Six-month Senkar mouse skin painting study (in lieu of a dermal subchronic study).

The Data Call-In (DCI) Notice will contain necessary information on experimental protocols to be used. Other studies may also be required by the DCI Notice.

Upon receipt and review of the above studies, additional studies, including exposure studies, may be required.

2. Existing stocks. Under the authority of FIFRA section 6(a)(1) and (b), EPA is establishing certain limitations on the sale, distribution and use of existing stocks of creosote and coal tar products subject to this cancellation Notice. EPA defines the term "existing stocks" to mean any quantity of creosote and coal tar nonwood preservative product in the United States on the date of EPA's Notice of Intent to Cancel that has been formulated, packaged and labeled for any nonwood preservative use and is being held for shipment or release or has been shipped or released into commerce.

EPA will allow the sale and distribution of existing stocks of creosote and coal tar nonwood preservative products for up to one year after publication of this Notice of Intent to Cancel

in the FEDERAL REGISTER. EPA also will allow use of those existing stocks for up to one year after publication of this Notice. EPA is requiring registrants to contact commercial distributors of creosote and coal tar products to inform them of the time limitations on distribution, sale, and use, and to provide supplemental labeling reflecting the time limitations for existing stocks in the possession of the commercial distributors.

Following expiration of the time limitations on distribution or sale of existing stocks, revised labeling will be required on the products for use to control gypsy moth egg masses. Upon expiration of the time limitation use of existing stocks, disposal would be in accordance with the requirements of the Resource Conservation and Recovery Act.

The Agency believes that only very small (if any) quantities of creosote and coal tar products for any nonwood preservative use are currently distributed into commerce. Therefore, these quantities are likely to be used up within one year and are unlikely to pose any unreasonable risk to humans or the environment in that year.

VI. PROCEDURAL MATTERS

This Notice announces the Agency's final decision to cancel all Federal registrations except those for control of gypsy moth egg masses and to deny all applications for nonwood preservative uses of products containing creosote and coal tar. Under sections 6(b)(1) and 3(c)(6) of FIFRA, applicants, registrants, and certain other adversely affected parties may request a hearing on the cancellation and denial actions that this

Notice initiates. Unless the registrant or applicant makes the required corrections stated in this Notice or a hearing is properly requested with regard to a particular registration or application, the registration will be cancelled or the application denied. This unit of the Notice explains how such persons may request a hearing and the consequences of requesting or failing to request a hearing in accordance with the procedures specified in this Notice.

A. PROCEDURE FOR REQUESTING A HEARING

To contest the regulatory actions set forth by this Notice, registrants, and any applicant whose applications for registration has been denied, may request a hearing within 30 days of receipt of this Notice, or within 30 days from the publication of this Notice in the FEDERAL REGISTER, whichever occurs later. Any other persons adversely affected by the cancellation action described in this Notice, or any interested person with the concurrence of an applicant whose application for registration has been denied, may request a hearing within 30 days of publication of this Notice in FEDERAL REGISTER.

All registrants, applicants, and other adversely affected persons who request a hearing must file the request in accordance with the procedures established by FIFRA and the Agency's Rules of Practice Governing Hearings (40 CFR Part 164). These procedures require that all requests must identify the specific registration(s) by registration number(s) and the specific use(s) for which a hearing is requested, and must be received by the Hearing Clerk within the applicable 30-day

period. Failure to comply with these requirements will result in denial of the request for a hearing. Requests for a hearing should also be accompanied by objections that are specific for each use of the pesticide product for which a hearing is requested.

Requests for a hearing must be submitted to:

Hearing Clerk (A-100),

Environmental Protection Agency

401 M St., SW.

Washington, D.C. 20460.

B. CONSEQUENCES OF FILING OR FAILING TO FILE A HEARING REQUEST

1. Consequences of filing a timely and effective hearing request. If a hearing on any action initiated by this Notice is requested in a timely and effective manner, the hearing will be governed by the Agency's Rules of Practice for Hearings under FIFRA section 6 (40 CFR Part 164). In the event of a hearing, each cancellation action concerning the specific use or uses of the specific registered product which is the subject of the hearing will not become effective except pursuant to an order of the Administrator at the conclusion of the hearing. Similarly, in the event of a hearing, each denial of registration which is a subject of the hearing will not become effective prior to the final order of the Administrator at the conclusion of the hearing.

The hearing will be limited to the specific registrations or applications for which the hearing is requested.

2. Consequences of failure to file in a timely and effective manner. If a hearing concerning the cancellation

or denial of registration of a specific nonwood preservative pesticide product subject to this Notice is not requested by the end of the applicable 30-day period, registration of that product will be cancelled, or the denial will be effective, unless the registrant or applicant files a request for an amended label within the statutory period provided herein. If a registrant wishes to contest the cancellation or required conditions for particular identified uses, but desires to modify the terms and conditions of registration to secure continued registration of one or more of those uses permitted by this Notice, the registrant must file a request to amend his label in accordance with the terms and conditions of registration set forth herein as well as submit the hearing request.

C. PROCEDURES REQUIRED FOR PRODUCTS REGISTERED PURSUANT TO 40 CFR 162.17

EPA is aware of a number of pesticide products containing creosote or coal tar for nonwood preservative uses which are not federally registered and which are being marketed under the authority of 40 CFR 162.17. The Agency hereby notifies all persons producing or distributing such products that they must submit a full application for Federal registration including all required supporting data as prescribed by the provisions of section 3 of FIFRA of 40 CFR Part 162 and of PR Notice 83-4 and 83-4a within 30 days of receipt of this Notice or publication in the FEDERAL REGISTER, whichever is later. The Agency further notifies all such applicants that only products which conform with the requirements of this Notice will be registered.

Any person who wishes to register a product which would not conform with the requirements of this Notice is informed that this Notice is a denial of his application, and that if he wishes to contest the denial, he must request a hearing within the applicable 30-day period provided by this Notice.

D. SEPARATION OF FUNCTIONS

The Agency's rules of practice forbid anyone who may take part in deciding this case, at any stage of the proceeding from discussing the merits of the proceeding ex parte with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives (40 CFR 164.7).

Accordingly, the following Agency offices, and the staffs thereof, are designated as the judicial function of the Agency in any administrative hearing on this Notice of Intent to Cancel: the Deputy Administrator, and the members of the staff in the immediate office of the Administrator. None of the persons designated as the judicial staff may have any ex parte communication with the trial staff or any other interested person not employed by EPA, on the merits of any of the issues involved in these proceeding, without fully complying with the applicable regulations.

Dated: 2 Oct 85

Assistant Administrator
for Pesticides
and Toxic Substances